

Soto reference. A human clinical trial is described in the second Tabuke Declaration, submitted herewith pursuant to 37 CFR 1.132.

In addition, the claimed composition has a surprisingly non-greasy feel and performs better than is a standard drug preparation for treatment of burns containing silver sulfadiazine (SSD). To briefly review, the first Tabuke Declaration, submitted December 2, 2002, showed that superficial burn patients took 11.3 days on average to heal using the SENCIL<sup>®</sup> preparation versus 15.8 days on average using SSD. Pain control was also better with the SENCIL<sup>®</sup> because 55 individuals or 88% of the burn patients experienced no pain on SENCIL<sup>®</sup> as opposed to only 50 individuals or 75% of the burn patients on SSD.

Claims 1, 2, 4-15, 17 and 24-27 are rejected under 35 USC 103(a) over George, in view of Soto, Ahrens, Kaplan and Slimak.

George discloses a medicinal preparation for skin containing a combination of cod liver oil and castor oil only. The fish oil is said to be a vehicle for the castor oil (Column 2, lines 24-26). The castor oil prevents the growth of scar tissue, and the fish oil controls the caustic action of the castor oil, while at the same time promoting the healing of the wound. (Column 2, lines 43-48). In contrast the components of the present invention corresponding to a "vehicle" are beeswax and an excipient like petroleum jelly. One would not be motivated to modify the composition of George by adding beeswax (or any of the other oils recited in the claims, i.e., olive oil, sunflower oil and almond oil in *specific* amounts) since cod liver oil is already serving the vehicle function.

Soto is cited for teaching the use of olive oil and beeswax to treat skin injuries. Slimak also teaches a composition comprising oil and beeswax for the treatment of skin.

Sencil ointment is representative of the present invention. The applicant has compared the efficacy of Sencil ointment and "Ointment B," which contains olive oil and beeswax in approximately equal proportions, in clinical trials to evaluate its effect on four skin conditions: itching, dryness, rash, and pain, in 60 patients. The results are summarized in Table 4 of the second Tabuke Declaration (submitted herewith) and reproduced below.

Table 4.

**OUTCOME MEASURES-day symptoms cleared**

|         |            | DAY 1 | DAY 2 | DAY 3 | DAY 4 | DAY 5 | Total |
|---------|------------|-------|-------|-------|-------|-------|-------|
| Symptom |            |       |       |       |       |       |       |
| Itching | Sencil     | 2     | 4     | 1     | 1     | 0     | 8     |
|         | Ointment B | 0     | 0     | 1     | 0     | 8     | 9     |
| Dryness | Sencil     | 3     | 5     | 2     | 0     | 0     | 10    |
|         | Ointment B | 0     | 0     | 1     | 3     | 4     | 8     |
| Rash    | Sencil     | 1     | 2     | 3     | 1     | 0     | 7     |
|         | Ointment B | 0     | 0     | 1     | 3     | 4     | 7     |
| Pain    | Sencil     | 1     | 3     | 1     | 0     | 0     | 5     |
|         | Ointment B | 0     | 0     | 1     | 2     | 3     | 6     |
|         |            |       |       |       |       |       | 60    |

One can see that the onset of relief occurred more quickly using Sencil in each trial.

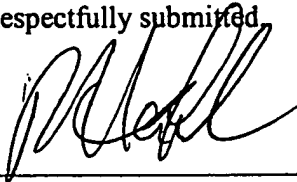
As the examiner has stated, neither George or the combination of Slimak, Soto and Kaplan teach compositions containing all of the claimed components. A person of skill in the art would not have been motivated to use all the claimed ingredients *in the recited concentrations*. at least because some are mentioned in the prior art as having the same functions (cod liver oil and petroleum are described as carriers) and there is nothing in the references to guide the selection of the claimed concentrations: one could not have predicted anything from the references about the excellent clinical results obtained by Dr. Tabuke, and the non-greasy feeling of the claimed mixture.

Accordingly, the claimed mixture consisting of five specific oils and beeswax in recited amounts would not have been obvious within the meaning of 35 USC 103(a).

**AUTHORIZATION**

Applicants believe there is no additional fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,



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Attachments: Declaration Under 37 CFR 1.132  
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Dated: December 5, 2005

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